

Amendments to the Claims

Please cancel claims 22-36 without prejudice.

The following listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A process to prepare an injectable sustained release pharmaceutical composition comprising:

preparing biodegradable porous microspheres comprising cationic functional groups from a mixture of a biocompatible material comprising cationic functional groups and a biodegradable polymer;

adding a solution comprising a biopharmaceutical compound to the biodegradable porous microspheres;

incorporating the biopharmaceutical compound into the biodegradable porous microspheres through ionic interaction by suspending or equilibrating the biodegradable porous microspheres in a solution comprising the biopharmaceutical compound at a pH beyond the pI of the biopharmaceutical compound; and

recovering and freeze-drying the biopharmaceutical-incorporated microspheres;

~~wherein the biopharmaceutical compound is over 5,000 dalton and is present in an amount of more than 10% by weight.~~

Claims 2-4 (Cancelled)

5. (Currently amended) The process of claim 1, wherein the biodegradable porous microsphere comprises one or more of polylactides, polyglycolides, poly(lactide-co-glycolide)s, polycaprolactone, polycarbonates, polyesteramides, polyanhydrides, poly(amino acids), polyorthoesters, polyacetyls, polycyanoacrylates, polyetheresters, poly(dioxanone)s, poly(alkylene alkylate)s, copolymers of polyethylene glycol and polyorthoester, biodegradable polyurethanes, proteins such as albumin, casein, collagen, fibrin, fibrinogen, gelatin, hemoglobin, transferrin, and ~~zero polysaccharides such as alginic acid, chitin, chitosan, chondroitin, dextrin, dextran, hyaluronic acid, heparin, keratmi sulfate, starch and derivatives or blends thereof~~ combinations thereof.

Claims 6-8 (Cancelled)

9. (Previously presented) The process of claim 1, wherein the cationic functional groups comprise primary, secondary, ternary, or quaternary amine groups.

10. (Previously presented) The process of claim 1, wherein the biocompatible material comprises a cationic surfactant.

11. (Previously presented) The process of claim 10, wherein the cationic surfactant comprises benzalkonium chloride, benzethonium chloride, or cetrimide.

Claim 12 (cancelled)

13. (Previously presented) The process of claims 1, wherein preparing biodegradable porous microspheres comprising cationic functional groups comprises solvent extraction or evaporation in aqueous or organic phase, phase separation, spray drying, low temperature casting, and supercritical gas fluid method.

14. (Previously presented) The process of claim 1, wherein porosity of the biodegradable porous microspheres comprising cationic functional groups is increased by addition of gas forming agents or salts such as sodium chloride, calcium chloride, and ammonium bicarbonate during microsphere preparation process.

15. (Previously presented) The process of claim 1, wherein preparing the biodegradable porous microspheres comprising cationic functional groups comprises co-addition of:

acidifying agents, wherein the acidifying agents comprise lactic acid, glycolic acid, tartaric acid, citric acid, fumaric acid, and malic acid; and

alkalizing agents, wherein the alkalizing agents comprise diethanolamine, mono ethanolamine, potassium citrate, sodium bicarbonate, calcium carbonate, magnesium carbonate, magnesium oxide, magnesium trisilicate, sodium citrate, meglumine, and triethanolamine and salts.

Claims 16-18 (Cancelled)

19. (Previously presented) The process of claim 1, further comprising coating the composition with one or more of gelatin, fibrin, or albumin.

20. (Previously presented) The process of claim 1, wherein the size of the biodegradable porous microspheres is within the range from 0.01 to 500 ppm.

21. (Currently amended) An injectable sustained release pharmaceutical composition, comprising:

a biodegradable porous microsphere, comprising cationic functional groups from a mixture of a biocompatible material comprising cationic functional groups and a biodegradable polymer; and

a biopharmaceutical compound, ~~wherein the biopharmaceutical compound is positioned in the biodegradable porous microspherewherein the biopharmaceutical compound is~~
incorporated into the biodegradable porous microspheres through ionic interactions; and

~~wherein the biopharmaceutical compound is over 5,000 dalton and is present in an amount of more than 10% by weight.~~

Claims 22-36: (Cancelled)